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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,519	05/10/2001	Donald E. Gillespie	DEG-10002/29	6344

7590

09/10/2003

John G. Posa
Gifford, Krass, Groh et al
280 N. Old Woodward Ave., Suite 400
Birmingham, MI 48009

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,519

Applicant(s)

GILLESPIE, DONALD E.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 9-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 9-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Office Action filed on June 10, 2003 ("hereinafter Response") has been entered.

Claims 9-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4. This application contains claims 9-21 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's petition to examine claims 9-21 pursuant to 37 CFR § 1.142(b) has been denied. Please see Paper No. 8 filed on July 24, 2003.

Claim Rejections - 35 USC § 112

Claims 8 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the invention" in 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

Claims 1-4, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by L'Esperance US Patent 5,300,020.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

Applicant argues that the device of L'Esperance is not a punctum plug. (see Response at page 1). In response Examiner states that L'Esperance discloses an implantable device for controlling drainage flow of aqueous fluid from the anterior chamber of the eye. Accordingly, the device of L'Esperance meets the limitations of the instant plug. (see figure 1, element # 17; col 2, lines 55-65). Applicant has not provided any evidence to prove otherwise.

Applicant further states that the "energy absorbing compound" in L'Esperance has nothing to do with visualization. In response Examiner states a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Here, L'Esperance teaches that his plug contains an energy-absorbing compound such as fluorescent or Rose Bengal at the tubular section of the plug. Accordingly, L'Esperance provides the same elements as the instant plug regardless of its intended use. Therefore, L'Esperance anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seder et al US Patent 4,959,048 or Freeman US Patent 3,949,750 in view of Gwon et al US Patent 5,178,635.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the combined teachings of references meet all the limitations of the instant claims.

Second, Applicant argues that there is no suggestion to combine the references. (see Response at page 2). In rebuttal Examiner states Applicant appears to be ignoring the general knowledge in the art about the use of ophthalmic plugs. In the instant case Seder and Freeman both teach punctual plugs that are flexible and suitable in dimension and of material to be inserted into punctual apertures. Gwon shows suitable dyes and fluorescent tracers have been used in the art as a means for improving visualization in ophthalmic devices. (col 5, lines 30-50). Gwon explicitly teaches that a tracer may be incorporated into the insert by physical admixture or dissolution into the implant matrix. (col 5, lines 47-50). Such tracer is able to illuminate with light at its own illumination wavelength (as required by the instant claims 5-7). Seder's and Freeman's punctual plugs are ophthalmic devices.

Accordingly, using a tracer, such as those taught by Gwon, in the matrix of an ophthalmic device, such as those taught by Seder and Freeman, is a general knowledge available in the art. Thus, even though neither Seder nor Freeman teach a

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tracer in their plug, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a tracer such as florescence into the matrix of Seder's or Freeman's plugs, because as taught by Gwon, the ordinary artisan would have had a reasonable expectation of success in improving the visualization of the plug in the recipient's eyes.

Finally, Applicant argues that there is no factual basis to support Examiner's conclusion of obviousness. (see Response at page 2). However, it is well settled in Patent Law that "[F]or obviousness under §103, all that is required is a reasonable expectation of success." *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985); *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). Here, the information in the Seder and Freeman references, when combined with the Gwon reference provided such a reasonable expectation of success.

Examiner informs Applicant that "[O]bviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious." *In re Merck & Co.*, 800 F.2d at 1098, 231 USPQ at 380; *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1461, 221 USPQ 481, 488 (Fed. Cir. 1984); *In re Papesch*, 315 F.2d 381, 386-87, 137 USPQ 43, 47-48 (CCPA 1963). Applicant has not provided any evidence showing

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nonobviousness. Accordingly, for the reasons of record the rejection is hereby maintained.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

SS
9/5/03


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200